High Short-Term Failure Rate Associated With Decellularized Osteochondral Allograft for Treatment of Knee Cartilage Lesions

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Purpose: To report the short-term clinical and radiographic outcomes following the use of decellularized osteochondral (OC) allograft plugs in the treatment of distal femoral OC lesions. **Methods:** An Institutional Review Board-approved database with prospectively collected data was used to identify patients treated with the decellularized OC allograft plugs implant. Demographic information, patient-reported outcomes, magnetic resonance imaging (MRI), and the number and type of reoperations were assessed. Failure was defined as revision surgery with removal of the implant. Patients were evaluated pre- and postoperatively using the Short Form-36, Activity of Daily Living Score, International Knee Documentation Committee Subjective Evaluation, Cincinnati Knee Rating System, and Marx Activity Scale. MRIs were evaluated using the OsteoChondral Allograft MRI Scoring System. **Results:** Thirty-four patients were identified, with a mean age of 45 (±11.9) years; 71% were male. Fifteen (44%) patients had undergone prior ipsilateral surgical intervention. Mean defect size was 4 (±1.5) cm^2, and median number of allografts per knee was 2 (range, 1-5). Mean follow-up duration was 15.5 months (range, 6-24). Ten patients (29%) required revision surgery with removal of the implant. Implant survivorship was 61% at 2 years. Female gender was independently predictive of failure, with a hazard ratio of 9.4 (95% confidence interval [CI], 2.0-58.9; $P = .005$). Defect size was also independently predictive of failure, with a hazard ratio of 1.9 per 1 cm^2 increase (95% CI, 1.2-3.1; $P = .005$). MRIs obtained at 1 year postoperatively demonstrated significantly improved osseous integration ($P = .0086$) and opposing cartilage ($P = .019$) in the nonfailure group as compared with the failure group. **Conclusions:** Based on the high short-term failure rate observed in this study, the authors advise that a decellularized OC allograft plugs implant should be used with caution in the treatment of OC lesions of the knee, as similar outcomes have not been noted with other cartilage restoration techniques. **Level of Evidence:** Level IV, therapeutic case series.

The incidence of symptomatic full-thickness cartilage lesions is increasing annually,[1] and the treatment of these defects remains a challenge, despite the numerous options available. Microfracture has historically been the most common method employed for cartilage restoration in the knee, in part due to the procedure's technical ease, low cost, and limited surgical morbidity. However, the fibrocartilage formed from this technique is less durable than native collagen, resulting in degradation over time, and has limited efficacy in the treatment of larger lesions (>2 cm^2).[2-4] Autologous chondrocyte implantation (ACI) has also been used to treat these lesions but is very expensive, is less successful with bone loss at the base of the lesion, and requires a 2-stage procedure for harvesting and implantation.[5,6] Osteochondral autograft transplant (OATS) has also been commonly used, but the procedure is associated with donor site morbidity and is limited by articular congruity mismatch.[7-9] Osteochondral allograft transplantation (OCA) eliminates the donor site morbidity and size limitations of OATS but is

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limited by allograft availability and a short shelf life following allograft specimen procurement. As such, the availability of viable osteochondral (OC) allografts remains limited for the vast majority of orthopaedic surgeons.[10]

To overcome the limitations characteristic of other chondral repair methods, a commercially produced decellularized OC allograft implant (Chondrofix; ZimmerBiomet, Warsaw, IN) was recently made available for the treatment of chondral defects. These allografts consist of decellularized hyaline cartilage and cancellous bone that are theorized to maintain the mechanical properties of unprocessed OC grafts. The graft undergoes lipid extraction and viral inactivation processing before being terminally sterilized with radiation. The grafts are readily available on the shelf, thus eliminating the challenging timing aspects associated with OCA use and the donor site morbidity associated with OATS.[11]

Despite these potential benefits, there is a paucity of data on the clinical utility of the product. Following an experimental equine study that supported decellularized OC allograft plugs for clinical use, there have been 2 case reports and 2 clinical series published in the English language.[11-14] The clinical performance of the implant is not clear from the limited data available, as one case series reported a failure rate of 8.2%[11] by 2 years and the other documented a 72% failure rate in the same time frame.[12]

The early clinical experience noted at our institution with the use of this implant compares unfavorably with the use of fresh OC allograft plugs. As a result, the authors felt compelled to analyze the short-term outcomes of patients treated with the decellularized OC allograft plugs. The purpose of this study was to report the short-term clinical and radiographic outcomes following the use of decellularized OC allograft plugs in the treatment of distal femoral OC lesions. The authors hypothesized that the early clinical and radiographic outcomes following the use of processed, acellular decellularized OC allograft plugs for the treatment of symptomatic articular cartilage lesions of the knee may be worse than has been previously reported in the literature.

Methods

Following Institutional Review Board approval, prospectively collected data from an internal registry were retrospectively reviewed. The registry at the authors' institution contains prospective data on all patients who have had cartilage reconstruction or repair procedures since 1999. From July 2014 to July 2015, 36 patients were identified who underwent treatment of a cartilage lesion with the decellularized OC allograft plugs implant by the senior author (C.C.J.). Indications for undergoing a cartilage restoration procedure included patients with at least one full-thickness (Outerbridge grade 4, International Cartilage Repair Society [ICRS] grade 4) symptomatic focal lesion of the femoral condyles or trochlea. The decision to proceed with the decellularized OC allograft plugs implant rather than other articular procedures was made by the patient after a comprehensive discussion of the options. Patients over 55 years of age were strongly encouraged to consider arthroplasty but were not deemed inappropriate candidates for the procedure solely on the basis of age. Patients with inflammatory arthritis, malalignment as assessed by physical exam and/or standing load-bearing radiographs, or significant uni- or tricompartmental arthritis were not considered candidates for the procedure.

Inclusion criteria were subject age between 18 and 65 years; at least one full-thickness symptomatic (Outerbridge grade 4, ICRS grade 4) cartilage lesion of the knee; and at least 6 months of follow-up postoperatively. Exclusion criteria were age greater than 65 years; partial-thickness or asymptomatic cartilage lesions of the knee; and less than 6 months of follow-up postoperatively.

Surgical Technique

All procedures were performed by a subspecialty-trained sports medicine surgeon (R.J.W.). Following arthroscopic evaluation of the involved knee, a medial or lateral arthrotomy was used based on defect location, and the defect was sized. The allograft implants were placed by first creating a recipient site on the affected condyle using a guide pin and reamer. Typical recipient site depth ranged from 8 to 11 mm. The recipient site depth was measured, and the decellularized OC allograft plugs implant was trimmed to match the measured depth. Decellularized OC allograft plugs implants were press fit into the recipient site. The articular cartilage layer of the implant matched the surrounding native articular cartilage, as shown in Figure 1. This process was repeated for additional plugs as indicated.

Postoperative Rehabilitation

Patients were made toe-touch weight bearing with crutches for the 2 weeks following the procedure. At 2 weeks postoperatively, patients were advanced to full weight bearing as tolerated with the use of a hinged knee brace. A standardized rehabilitation protocol with an emphasis on quadriceps strengthening and knee range of motion under the supervision of a physical therapist commenced for all patients between 7 and 10 days postoperatively.

Follow-up Investigations

As per the registry protocol, an independent observer collected data before surgery and at the following postoperative follow-up intervals: 6 months, 1 year, and 2 years. The clinical assessment was performed with validated, knee-specific outcome instruments after knee articular cartilage repair[15] and included Activity of